

## **EXHIBIT 5, Tab F**

**F**

**Waterman, Sharon**

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**From:** HOLOVACM@cder.fda.gov  
**Sent:** Thursday, July 29, 2004 7:01 AM  
**To:** Jamie.Szturo@sanofi-aventis.com; HOLOVACM@cder.fda.gov  
**Cc:** FRIEDMANB@cder.fda.gov; HARE@cder.fda.gov; JONESM@cder.fda.gov  
**Subject:** Arava

Ms. Szturo,

This was discussed internally and agreed upon that YES, it does fall into "marketing." Please send a letter to the OB staff as detailed below asking us to move it to the active Rx list.

Thank you.

Mary Ann Holovac

-----Original Message-----

**From:** Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]  
**Sent:** Wednesday, July 28, 2004 2:17 PM  
**To:** HOLOVACM@cder.fda.gov  
**Cc:** FRIEDMANB@cder.fda.gov  
**Subject:** RE: Orange Book Update  
**Importance:** High

-----Original Message-----

**From:** Szturo, Jamie PH/US  
**Sent:** Tuesday, July 27, 2004 1:09 PM  
**To:** 'Holovac, Mary Ann'  
**Cc:** Friedman, Beverly J  
**Subject:** RE: Orange Book Update

Mary Ann,

This is a "Physician Starter Sample" only - does that fall into 'marketing'?

-----Original Message-----

**From:** Holovac, Mary Ann [mailto:HOLOVACM@cder.fda.gov]  
**Sent:** Tuesday, July 27, 2004 1:07 PM  
**To:** Szturo, Jamie PH/US; Holovac, Mary Ann  
**Cc:** Friedman, Beverly J  
**Subject:** RE: Orange Book Update

send the OB staff a letter asking us to move it to the Rx section if you are marketing it.

7500 Standish Place  
Rockville, MD 20855

Than ks.

-----Original Message-----

**From:** Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]  
**Sent:** Tuesday, July 27, 2004 2:05 PM  
**To:** HOLOVACM@cder.fda.gov  
**Cc:** FRIEDMANB@cder.fda.gov

6/9/2005

**Subject:** RE: Orange Book Update

Mary Ann,

What do I need to do to have the 100mg moved to active?

-----Original Message-----

**From:** Holovac, Mary Ann [mailto:HOLOVACM@cder.fda.gov]

**Sent:** Tuesday, July 27, 2004 12:26 PM

**To:** Szturo, Jamie PH/US; Holovac, Mary Ann

**Cc:** Friedman, Beverly J

**Subject:** RE: Orange Book Update

they are all listed in the Orange Book-the 100mg is on the disc list, the other two potencies on the rx list

-----Original Message-----

**From:** Jamie.Szturo@aventis.com [mailto:Jamie.Szturo@aventis.com]

**Sent:** Tuesday, July 27, 2004 12:06 PM

**To:** holovacm@cder.fda.gov

**Cc:** friedmanb@cder.fda.gov

**Subject:** Orange Book Update

**Importance:** High

Dear Mary Ann,

I am following up with you regarding a phone call I received today from Mrs. Friedman.

I need to confirm that for NDA 20-905 - Arava the following dosages should be listed:

10mg

20mg

100mg

Thank you

*Jamie Szturo*

*Aventis Pharmaceuticals Inc.*

*US Regulatory CMC - J5-M1540*

*10236 Marion Park Drive*

*Kansas City, Mo 64137*

*816-966-5920*

*816-966-6794 fax*

*Nextel 816-564-3560*

*Jamie.Szturo@aventis.com*

**Visit RCMC Web:** [http://draprdwww.brw.hmrag.com/grams/page\\_item.asp?page\\_id=23](http://draprdwww.brw.hmrag.com/grams/page_item.asp?page_id=23)